



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES,  
AND TOXIC SUBSTANCES

**MEMORANDUM**

Date: November 18, 2005

Subject: Triadimenol. Acute and Chronic Dietary Exposure Assessments for the Tolerance Reassessment Eligibility Decision (TRED) Document.

DP Barcode: D314928  
40 CFR §: 180.450

PC Code: 127201  
Chemical Class: Azole

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## Executive Summary

Acute and chronic dietary (food and water) exposure assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 2.03), which uses food consumption data from the USDA's Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994-1996 and 1998. The acute and chronic dietary risk assessments were conducted for all supported triadimenol food uses and were performed to support the tolerance reassessment eligibility decision document.

Triadimenol,  $\beta$ -(4-chlorophenoxy)- $\alpha$ -(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol, is a systemic fungicide registered for use in the United States as a seed treatment for barley, corn, cotton, oats, rye, and wheat. Additionally, an import tolerance on bananas has been established. Triadimenol end-use products are marketed in the U.S. under the trade name Baytan®. The reregistration of triadimenol is being supported by Bayer CropScience, the basic producer.

### Acute Dietary Exposure Results and Characterization of Input Data

A refined acute dietary exposure assessment was conducted to estimate the dietary risks associated with the reregistration of triadimenol. The acute dietary exposure assessment incorporated a DEEM Version 7.81 default processing factor for dried bananas along with the available data from the processing studies and 100% crop treated. The anticipated residue (AR) estimate for bananas is based on the available field trial data while incorporating existing tolerance values for the remaining commodities. The assessment also included the peak surface water concentration. Acute dietary risk estimates are provided for the general U.S. population and various population subgroups, with the major emphasis placed on the exposure estimates for infants and children. This assessment concludes that for all supported commodities, the acute dietary risk estimates do not exceed HED's level of concern (less than 100% of the aPAD) at the 95<sup>th</sup> exposure percentile for the U.S. population (15% of the aPAD) and all population subgroups, with the highest exposed population subgroup being children 1-2 years old at 29% of the aPAD.

### Chronic Dietary Exposure Results and Characterization of Input Data

A conservative chronic dietary exposure assessment was conducted to estimate the dietary risks associated with the reregistration of triadimenol. The chronic dietary exposure assessment incorporated a DEEM Version 7.81 default processing factor for dried bananas along with the available data from the processing studies. Existing tolerance level residues, 100% crop treated, and the highest 1 in 10 year annual mean drinking water concentration were used to conduct this conservative assessment. Chronic dietary risk estimates are provided for the general U.S. population and various population subgroups, with the major emphasis placed on the exposure estimates for infants and children. This assessment concludes that for all supported commodities, the chronic dietary risk estimates do not exceed HED's level of concern (less than 100% of the cPAD) for the U.S. population (7% of the cPAD) and all population subgroups, with the highest exposed population subgroup being children 1-2 years old at 23% of the cPAD.

### Aggregate Exposure to Triadimefon and Triadimenol

Exposure to triadimenol can occur following the application of triadimenol as an active ingredient

as well as from the metabolism/degradation of triadimefon. The current dietary risk assessment only addresses the use of triadimenol as an active ingredient per se. Exposures from the pesticidal uses of triadimenol have not been aggregated with triadimenol exposures reflecting metabolism and/or degradation of triadimefon because risks attributable to uses of triadimefon already exceed HED's level of concern (S. Ary, D314778, 11/23/2005) and because the resulting apparent increase in aggregate risk would unduly be associated with the registered uses of triadimenol. The Agency is soliciting comments on assumptions used in the current risk assessment. Should refinements be possible in the future, it may be appropriate to aggregate multiple routes and sources of exposures for these chemicals.

## **I. Introduction**

Dietary risk assessment incorporates both exposure and toxicity of a given pesticide. For acute and chronic assessments, the risk is expressed as a percentage of a maximum acceptable dose (i.e., the dose which the Health Effects Division has concluded will result in no unreasonable adverse health effects). This dose is referred to as the population adjusted dose (PAD). The PAD is equivalent to the Reference Dose (RfD) divided by the special FQPA Safety Factor.

For acute and non-cancer chronic exposures, HED is concerned when estimated dietary risk exceeds 100% of the PAD. References which discuss the acute and chronic dietary risk assessments in more detail are available on the EPA pesticides web site: "Available Information on Assessing Exposure from Pesticides, A User's Guide," 6/21/2000, web link: <http://www.epa.gov/fedrgstr/EPA-PEST/2000/July/Day-12/6061.pdf>; or see SOP 99.6 (8/20/1999).

## **II. Residue Information**

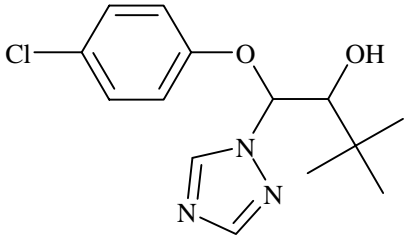
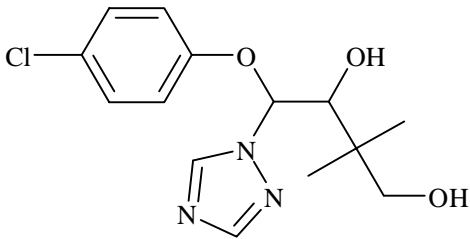
The reregistration requirements for plant metabolism have not been fulfilled. No metabolism studies with triadimenol have been submitted, however, metabolism studies with triadimefon have been received and reviewed. HED has determined that translation of metabolism data from triadimefon to triadimenol is not appropriate for the existing uses on cereal grains and cotton. The metabolism studies with triadimefon were conducted using a foliar application and triadimenol is used only as a seed treatment. Additionally, in the submitted triadimenol seed treatment wheat study, residues were not identifiable due to the low activity found in wheat grain. Therefore, HED concludes that the nature of the residue in cereal grains is not adequately understood; however, based on chemical structure and the probable metabolic pathway of triadimenol, the residues of concern for tolerance expression and risk assessment are likely to be triadimenol, KWG 1342, and KWG 1732 in/on cereal grains (barley, corn, oats, rye, and wheat) and cotton. The wheat metabolism data conducted with triadimefon indicate that KWG 1732 is the major metabolite found in grain at 35% TRR and KWG 1342 at 21% TRR in grain. Triadimenol accounted for 12% TRR. It is also noted that the submitted wheat processing study conducted with triadimenol applied as a seed treatment identified quantifiable residues of KWG 1732. There have been no previous triazole labeled studies conducted with triadimenol applied as a seed treatment to commodities and data from the available soil metabolism studies conducted with triadimefon indicate that soil microbes metabolize the triazole fungicide to free triazole, which may be taken up into the plant. Separate metabolism studies with triazole-<sup>14</sup>C and phenyl-<sup>14</sup>C labeled triadimenol applied as a seed treatment to corn or wheat and cotton should be

conducted to confirm the residues of concern.

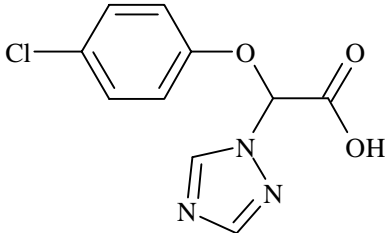
The residues of concern for tolerance expression and risk assessment for bananas are triadimenol and KWG 1342, which are based on the available metabolism data conducted with triadimefon applied to an established grape vine and the field trial data conducted with triadimenol applied to the soil of banana groves. The metabolism data conducted with triadimefon applied to grapes indicate that triadimenol is the major metabolite identified at 56% along with KWG 1342 at 16%. The available field trial data indicate that residues of triadimenol and KWG 1342 are both likely to be found in/on bananas.

HED has determined that only triadimenol in drinking water should be considered in the dietary risk assessment; it was the major residue found in the available triadimefon aerobic soil metabolism study (MRID 41686102).

Triadimenol is not registered for use as a direct livestock treatment. The nature of the residue in livestock is adequately defined for the current uses. HED concludes that the supported uses on barley, corn, cotton, oats, rye, and wheat result in a 40 CFR §180.6(a)(3) situation for ruminant commodities; i.e., there is no reasonable expectation of finite residues in ruminant commodities. The structure of triadimenol and metabolites of concern are presented in Table 1. Summary of the decisions concerning the residues of concern in plants and drinking water are presented below in Table 2.

Table 1. Chemical Names and Structures of Triadimenol and Its Metabolites.	
Common name and chemical name	Chemical structure
Triadimenol (KWG 0519)  $\beta$ -(4-chlorophenoxy)- $\alpha$ -(1,1-dimethylethyl)-1H-1,2,4-triazole-1-ethanol	
KWG 1342  1-(4-chlorophenoxy)-3,3-dimethyl-3-hydroxymethyl-1-(1H-1,2,4-triazol-1-yl)-2-butanol	

**Table 1. Chemical Names and Structures of Triadimenol and Its Metabolites.**

Common name and chemical name	Chemical structure
KWG 1732  1-(4-chlorophenoxy)-1-(1H-1,2,4-triazol-1-yl)ethanoic acid	

**Table 2. Summary of Metabolites and Degradates to be Included in the Risk Assessment and Tolerance Expression for Triadimenol.**

Matrix		Residues Included in Risk Assessment	Residues Included in Tolerance Expression
Plants	Primary crop - cereal grains and cotton	triadimenol, KWG 1342, and KWG 1732	triadimenol, KWG 1342, and KWG 1732
	Primary crop - banana	triadimenol and KWG 1342	triadimenol and KWG 1342
	Rotational crop	triadimenol, KWG 1342, and KWG 1732	triadimenol, KWG 1342, and KWG 1732
Livestock	Ruminant	NA	NA
	Poultry	NA	NA
Drinking water		triadimenol	NA

A summary of the triadimenol tolerance reassessment and recommended modifications in commodity definitions is presented in Table 3 (S. Ary, D314891, 11/17/2005).

**Table 3. Tolerance Reassessment Summary for Triadimenol.**

Commodity	Current Tolerance, ppm	Reassessed Tolerance, ppm	Comment [Correct Commodity Definition]
<b>Tolerances Established Under 40 CFR §180.450 (a)</b>			
Banana (whole) <sup>1</sup>	0.2	0.2	
Barley, grain	0.05	TBD <sup>2,3</sup>	
Barley, straw	0.2	TBD	
Corn, forage	0.05	TBD	[Corn, field, forage] [Corn, sweet, forage]
Corn, fresh (including sweet), (K+CWHR)	0.05	TBD	[Corn, sweet, K+CWHR]
Corn, grain	0.05	TBD	[Corn, field, grain] [Corn, pop, grain]

<b>Table 3. Tolerance Reassessment Summary for Triadimenol.</b>			
Commodity	Current Tolerance, ppm	Reassessed Tolerance, ppm	Comment <i>[Correct Commodity Definition]</i>
Corn, stover	0.05	TBD	<i>[Corn, field, stover]</i> <i>[Corn, pop, stover]</i> <i>[Corn, sweet, stover]</i>
Cotton, forage	0.02	Revoke	No longer considered a significant livestock feed item.
Cotton, undelinted seed	0.02	TBD	
Oat, forage	2.5	TBD	
Oat, grain	0.05	TBD	
Oat, straw	0.2	TBD	
Rye, forage	2.5	TBD	
Rye, grain	0.05	TBD	
Rye, straw	0.1	TBD	
Sorghum, forage, hay	0.05	Revoke	Bayer does not intend to support use of triadimenol on sorghum.
Sorghum, grain	0.01	Revoke	Bayer does not intend to support use of triadimenol on sorghum.
Sorghum, grain, stover	0.01	Revoke	Bayer does not intend to support use of triadimenol on sorghum.
Wheat, forage	2.5	TBD	
Wheat, grain	0.05	TBD	
Wheat, straw	0.2	TBD	
<b>Tolerances Established Under 40 CFR §180.450 (b)</b>			
Cattle, fat	0.1	Revoke	The available data indicate that tolerances for cattle commodities are not required.
Cattle, meat	0.1		
Cattle, meat byproducts	0.1		
Egg	0.01	Revoke	The available data indicate that a tolerance for eggs is not required.
Goat, fat	0.1	Revoke	The available data indicate that tolerances for goat commodities are not required.
Goat, meat	0.1		
Goats, meat byproducts	0.1		
Hog, fat	0.1	Revoke	The available data indicate that tolerances for hog commodities are not required.
Hog, meat	0.1		

**Table 3. Tolerance Reassessment Summary for Triadimenol.**

Commodity	Current Tolerance, ppm	Reassessed Tolerance, ppm	Comment <i>[Correct Commodity Definition]</i>
Hog, meat byproducts	0.1		
Horse, fat	0.1	Revoke	The available data indicate that tolerances for horse commodities are not required.
Horse, meat	0.1		
Horse, meat byproducts	0.1		
Milk	0.01	Revoke	The available data indicate that a tolerance for milk is not required.
Poultry, fat	0.01	Revoke	The available data indicate that tolerances for poultry commodities are not required.
Poultry, meat	0.01		
Poultry, meat byproducts	0.01		
Sheep, fat	0.1	Revoke	The available data indicate that tolerances for sheep commodities are not required.
Sheep, meat	0.1		
Sheep, meat byproducts	0.1		
Tolerances To Be Proposed Under 40 CFR §180.450 (a)			
Barley, hay	None established	TBD	
Cotton, gin byproducts	None established	TBD	
Oat, hay	None established	TBD	
Wheat, hay	None established	TBD	

1. 40 CFR §180.450(a) states that there are no U.S. registrations for banana (whole) as of 9/22/93.

2. TBD = To be determined.

3. Crop field trial data depicting residues of triadimenol, KWG 1342, and KWG 1732 in/on field corn (forage, grain, stover), sweet corn (forage, K+CWHR, grain, and stover), cotton (undelinted seed and gin byproducts), and wheat (forage, grain, hay, and straw) grown from seed treated at the maximum rate are required pending the results from the requested metabolism studies.

#### Residue Data used for Acute and Chronic Dietary Assessments

The anticipated residue estimates for the acute dietary assessment are based on the available field trial data for bananas while incorporating existing tolerance values for the remaining commodities. A residue distribution file (RDF) was used for bananas along with 100% CT. Tolerance values were used for barley, corn, cotton, oats, rye, and wheat to likely account for all residues of concern (triadimenol, KWG 1342, and KWG 1732), since field trial studies sampled for triadimenol and KWG 1342 only. The average residue from the submitted field trials conducted with wheat (MRID 42712101) is 0.0125 ppm (higher than the field trials conducted with barley and oats). If the available metabolism data for wheat grain is considered (35% of KWG 1732 was identified, triadimenol was found at 6%, and KWG 1342 at 21%), the highest average residue expected for KWG 1732 would be 0.0162 ppm, thus yielding a total residue of 0.03 ppm (0.0125

ppm + 0.0162 ppm), which is less than the existing tolerance of 0.05 ppm. Crop field trial data depicting the potential for concentration of triadimenol residues of concern in/on field corn processed commodities (MRID 44519801) and cotton processed commodities (MRID 44519802) indicate that residues of triadimenol, KWG 1342, and KWG 1732 were nonquantifiable (<0.05 for corn and <0.02 for cotton) following treatment at 5x the maximum application rate. Additionally, the field trial data submitted for corn and cotton demonstrate that residues of triadimenol and KWG 1342 were less than the method LOD of 0.01 for corn grain and cotton seed. Therefore, using tolerance values for corn grain (0.05 ppm) and cotton seed (0.02 ppm) are not expected to underestimate exposure. Tolerance values were used for the chronic dietary assessment.

### Processing Factors

Data from the processing studies were used in this assessment for several commodities along with a DEEM Version 7.81 default processing factor for dried banana (3.9x). Processing studies for field corn and cotton indicate that residues of triadimenol, KWG 1342, and KWG 1732 were non-quantifiable following treatment at 5x the maximum application rate; therefore, processing studies for these commodities were not conducted. A processing factor of 2.1x was utilized for barley, oat, and wheat bran. All other processed commodities showed little or no concentration in the available processing studies. For detailed considerations of processing factors see “Triadimenol. Summary of Analytical Chemistry and Residue Data for the Tolerance Reassessment Eligibility Decision (TRED) Document” under guideline section 860.1520 (S. Ary, D314891, 11/17/2005).

### Usage Information

No usage data are available for triadimenol, so 100% crop treated were assumed for all commodities.

### Residue Estimates for Individual Crops

The anticipated residue estimates for the acute dietary exposure assessment are based on the available field trial data for bananas while incorporating existing tolerance values for the remaining commodities. Existing tolerances were used for the chronic dietary exposure assessment. All triadimenol acute and chronic residue estimates for crop commodities are listed in Attachment 1.

## **III. Drinking Water Data**

The drinking water values used in the dietary risk assessment were provided by the Environmental Fate and Effects Division (EFED) in the following memorandum: “TRED for Triadimenol (PC # 127201) Drinking Water Assessment Environmental Fate and Effects Division” (J. Breithaupt, D321519, 2/9/2005). Water residues were incorporated in the DEEM-FCID™ into the food categories “water, direct, all sources” and “water, indirect, all sources”.

The estimated surface drinking water concentrations (EDWCs) for triadimenol were moderately refined and calculated using PRZM (Pesticide Root Zone Model) and EXAMS (Exposure Analysis Modeling System) for use in the human health risk assessment. The estimated groundwater concentrations for triadimenol were unrefined and calculated using SCI-GROW (Screening Concentration In Ground Water), however, were not used in the assessment because



residues are shown to be much higher in surface water.

The EDWCs were calculated from the use of triadimenol as a seed treatment to wheat, corn, and cotton. The wheat scenario produced the highest concentrations and is used in this dietary assessment. Only triadimenol in drinking water is considered in the dietary risk assessment; it was the major residue found in the available triadimefon aerobic soil metabolism study. Other degradates (e.g., CPMT or chlorophenoxymethyltriazole or 4-chlorophenoxy-1,2,4-triazol-1-yl-methane) are not considered in this assessment because there is insufficient data on the specific rates and locales of formation and conditions under which formation occurs to evaluate secondary degradates as part of total triadimenol residues; however, based on current information, other degradates are not at this time considered to be essential components of this drinking water evaluation.

#### Acute Dietary Assessment

The 30 year annual peak surface water concentration of 0.000393 ppm was used for the acute dietary assessment.

#### Chronic Dietary Assessment

The 1 in 10 year annual mean surface water concentration of 0.000194 ppm was used for the chronic dietary assessment.

### **IV. DEEM-FCID™ Program and Consumption Information**

Triadimenol acute and chronic dietary exposure assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™, Version 2.03), which incorporates consumption data from USDA's Continuing Surveys of Food Intakes by Individuals (CSFII), 1994-1996 and 1998. The 1994-96, 98 data are based on the reported consumption of more than 20,000 individuals over two non-consecutive survey days. Foods "as consumed" (e.g., apple pie) are linked to EPA-defined food commodities (e.g. apples, peeled fruit - cooked; fresh or N/S; baked; or wheat flour - cooked; fresh or N/S, baked) using publicly available recipe translation files developed jointly by USDA/ARS and EPA. For chronic exposure assessment, consumption data are averaged for the entire U.S. population and within population subgroups, but for acute exposure assessment are retained as individual consumption events. Based on analysis of the 1994-96, 98 CSFII consumption data, which took into account dietary patterns and survey respondents, HED concluded that it is most appropriate to report risk for the following population subgroups: the general U.S. population, all infants (less than 1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, adults 20-49, females 13-49, and adults 50+ years old.

For chronic dietary exposure assessment, an estimate of the residue level in each food or food-form (e.g., orange or orange juice) on the food commodity residue list is multiplied by the average daily consumption estimate for that food/food form to produce a residue intake estimate. The resulting residue intake estimate for each food/food form is summed with the residue intake estimates for all other food/food forms on the commodity residue list to arrive at the total average estimated exposure. Exposure is expressed in mg/kg body weight/day and as a percent of the

cPAD. This procedure is performed for each population subgroup.

For acute exposure assessments, individual one-day food consumption data are used on an individual-by-individual basis. The reported consumption amounts of each food item can be multiplied by a residue point estimate and summed to obtain a total daily pesticide exposure for a deterministic exposure assessment, or “matched” in multiple random pairings with residue values and then summed in a probabilistic assessment. The resulting distribution of exposures is expressed as a percentage of the aPAD on both a user (i.e., only those who reported eating relevant commodities/food forms) and a per-capita (i.e., those who reported eating the relevant commodities as well as those who did not) basis. In accordance with HED policy, per capita exposure and risk are reported for all tiers of analysis. However, for tiers 1 and 2, any significant differences in user vs. per capita exposure and risk are specifically identified and noted in the risk assessment.

## V. Toxicological Information

A summary of the toxicological doses and endpoints selected for the dietary exposure assessments are provided in Table 4.

Table 4. Summary of Toxicological Doses and Endpoints for Triadimenol. <sup>1,2</sup>			
Exposure Scenario	Dose Used in Risk Assessment, UF	Special FQPA SF* and Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute Dietary (general population)	NOAEL = 3.4 mg/kg/day UF = 1000 Acute RfD = 0.0034 mg/kg/day	FQPA SF = 1X aPAD = <u>acute RfD</u> FQPA SF = 0.0034 mg/kg/day	Subchronic neurotoxicity study in rats. LOAEL = 54.6/68.7 mg/kg/day based largely on hyperactivity.
Chronic Dietary (all populations)	NOAEL = 3.4 mg/kg/day UF = 1000 Acute RfD = 0.0034 mg/kg/day	FQPA SF = 1X cPAD = <u>chronic RfD</u> FQPA SF = 0.0034 mg/kg/day	Subchronic neurotoxicity study in rats. LOAEL = 54.6/68.7 mg/kg/day based largely on hyperactivity.
Cancer (oral, dermal, inhalation)	Classification: Category C “possible human carcinogen” based on increased incidence of hepatocellular adenomas in females.		

1. Triadimenol: HED Chapter of the Tolerance Reassessment Eligibility Decision (TRED) Document. PC Code: 127201, CAS Reg. No. 55219-65-3, DP Barcode: D314964. 11/23/2005.

2. UF = uncertainty factor, FQPA SF = Special FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic) RfD = reference dose, MOE = margin of exposure, LOC = level of concern, NA = Not Applicable.

## VI. Results/Discussion

As stated above, for acute and chronic assessments, HED is concerned when dietary risk exceeds 100% of the PAD. The DEEM-FCID™ analyses estimate the dietary exposure of the U.S. population and various population subgroups. The acute dietary exposure analysis results

reported in Table 4 are for the general U.S. population, all infants (less than 1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, adults 20-49, adults 50+ years, and females 13-49. The chronic dietary exposure analysis results reported in Table 5 are for the general U.S. population, all infants (less than 1 year old), children 1-2, children 3-5, children 6-12, youth 13-19, adults 20-49, adults 50+ years, and females 13-49. Cancer risk is determined for the general U.S. population only.

### Results of Acute Dietary Exposure Analysis

This assessment concludes that for all supported commodities, the acute dietary risk estimates do not exceed HED's level of concern (less than 100% of the aPAD) at the 95<sup>th</sup> exposure percentile for the U.S. population (15% of the aPAD) and all population subgroups, with the highest exposed population subgroup being children 1-2 years old at 29% of the aPAD. The results of the acute dietary exposure analysis at the 95<sup>th</sup>, 99<sup>th</sup>, and 99.9<sup>th</sup> percentiles of exposure are reported in Table 5. The results of the acute dietary exposure analysis at the 95<sup>th</sup> percentile are reported in Table 6 along with chronic dietary exposure analyses for easy comparison.

The acute dietary risk estimates for food alone (no water) do not exceed HED's level of concern at the 95<sup>th</sup> exposure percentile for the U.S. population (15% of the aPAD) and all population subgroups, with the highest exposed population subgroup being children 1-2 years old at 28% of the aPAD. The results of the food alone acute dietary exposure analysis at the 95<sup>th</sup> percentile are reported in Table 7 along with food alone chronic dietary exposure analysis for easy comparison.

<b>Table 5. Results of Acute (Food and Water) Dietary Exposure Analysis for Triadimenol Using DEEM-FCID.</b>							
Population Subgroup	aPAD (mg/kg/day)	95 <sup>th</sup> Percentile		99 <sup>th</sup> Percentile		99.9 <sup>th</sup> Percentile	
		Exposure (mg/kg/day)	% aPAD*	Exposure (mg/kg/day)	% aPAD*	Exposure (mg/kg/day)	% aPAD*
General U.S. Population	0.0034	0.000501	15	0.000791	23	0.001245	37
All Infants (< 1 year old)	0.0034	0.000798	23	0.001244	37	0.001657	49
Children 1-2 years old	0.0034	<b>0.000981</b>	<b>29</b>	<b>0.001367</b>	<b>40</b>	<b>0.002047</b>	<b>60</b>
Children 3-5 years old	0.0034	0.000871	26	0.001158	34	0.001609	47
Children 6-12 years old	0.0034	0.000639	19	0.000857	25	0.001220	36
Youth 13-19 years old	0.0034	0.000436	13	0.000623	18	0.001026	30
Adults 20-49 years old	0.0034	0.000329	10	0.000489	14	0.000739	22
Adults 50+ years old	0.0034	0.000249	7	0.000340	10	0.000515	15
Females 13-49 year old	0.0034	0.000318	9	0.000439	13	0.000718	21

The **bolded** values represent the highest exposed populations for each percentile.

### Results of Chronic Dietary Exposure Analysis

This assessment concludes that for all supported commodities, the chronic dietary risk estimates do not exceed HED's level of concern (less than 100% of the cPAD) for the U.S. population (7% of the cPAD) and all population subgroups, with the highest exposed population subgroup being children 1-2 years old at 23% of the cPAD. The results of the chronic dietary exposure analysis

are reported below in Table 6.

<b>Table 6. Summary of Acute and Chronic (Food and Water) Dietary Exposure and Risk for Triadimenol.</b>				
Population Subgroup	Acute Dietary (95 <sup>th</sup> Percentile)		Chronic Dietary	
	Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	% cPAD
General U.S. Population	0.000501	15	0.000251	7
All Infants (< 1 year old)	0.000798	23	0.000469	14
Children 1-2 years old	<b>0.000981</b>	<b>29</b>	<b>0.000770</b>	<b>23</b>
Children 3-5 years old	0.000871	26	0.000610	18
Children 6-12 years old	0.000639	19	0.000379	11
Youth 13-19 years old	0.000436	13	0.000224	7
Adults 20-49 years old	0.000329	10	0.000188	6
Adults 50+ years old	0.000249	7	0.000178	5
Females 13-49 years old	0.000318	9	0.000181	5

The **bolded** values represent the highest exposed populations for each of the risk assessments.

The chronic dietary risk estimates for food alone (no water) do not exceed HED's level of concern for the U.S. population (7% of the cPAD) and all population subgroups, with the highest exposed population subgroup being children 1-2 years old at 23% of the cPAD. The results of the food alone chronic dietary exposure analysis are reported below in Table 7 along with food alone acute dietary exposure analysis at the 95<sup>th</sup> percentile for easy comparison.

<b>Table 7. Summary of Acute and Chronic (Food Only) Dietary Exposure and Risk for Triadimenol.</b>				
Population Subgroup	Acute Dietary (95 <sup>th</sup> Percentile)		Chronic Dietary	
	Exposure (mg/kg/day)	% aPAD	Exposure (mg/kg/day)	% cPAD
General U.S. Population	0.000494	15	0.000247	7
All Infants (< 1 year old)	0.000763	22	0.000456	13
Children 1-2 years old	<b>0.000961</b>	<b>28</b>	<b>0.000764</b>	<b>23</b>
Children 3-5 years old	0.000862	25	0.000604	18
Children 6-12 years old	0.000633	19	0.000375	11
Youth 13-19 years old	0.000428	13	0.000221	7
Adults 20-49 years old	0.000320	9	0.000185	5
Adults 50+ years old	0.000240	7	0.000174	5
Females 13-49 years old	0.000309	9	0.000177	5

The **bolded** values represent the highest exposed populations for each of the risk assessments.

## **VII. Characterization of Inputs/Outputs**

The acute and chronic dietary exposure assessments were refined through the use of experimentally determined processing factors and a DEEM Version 7.81 default processing factor for dried bananas. The AR estimate used for bananas is considered moderately refined, although it is considered highly conservative based on the nature of the residue data source since field trial studies use maximum application rates and minimum pre-harvest intervals. Additionally, tolerance values were used for the remaining commodities for the acute analysis and for all commodities in the chronic assessment, and 100% crop treated was assumed for all commodities. HED concludes that the exposure estimates provided in this document are unlikely to underestimate actual exposure.

## **VIII. Conclusions**

The acute and chronic dietary risk assessments were conducted for all supported triadimenol food uses and were performed to support the tolerance reassessment eligibility decision document. The acute and chronic assessments show that dietary exposure and risk are of concern for the supported uses. However, exposure to triadimenol can occur following the application of triadimenol as an active ingredient as well as from the metabolism/degradation of triadimefon. The current dietary risk assessment only addresses the use of triadimenol as an active ingredient per se. Exposures from the pesticidal uses of triadimenol have not been aggregated with triadimenol exposures reflecting metabolism and/or degradation of triadimefon because risks attributable to uses of triadimefon already exceed HED's level of concern (S. Ary, D314778, 11/23/2005) and because the resulting apparent increase in aggregate risk would unduly be associated with the registered uses of triadimenol. The Agency is soliciting comments on assumptions used in the current risk assessment. Should refinements be possible in the future, it may be appropriate to aggregate multiple routes and sources of exposures for these chemicals.

## **IX. List of Attachments**

- Attachment 1. Data and Residue Estimates Used in Dietary Analyses.
- Attachment 2. Acute Food and Water Residue Input File.
- Attachment 3. Acute Food and Water Results File.
- Attachment 4. Acute Food Only Results File.
- Attachment 5. Chronic Food and Water Residue Input File.
- Attachment 6. Chronic Food and Water Results File.
- Attachment 7. Chronic Food Only Results File.

<b>Attachment 1. Data and Residue Estimates Used in Dietary Analyses.</b>											
RAC	Classification <sup>1</sup>	Data Source	MRID	No. of Samples	No. of Detectable Residues	Avg. LOD (ppm)	% CT Avg. <sup>2</sup>	% CT Max. <sup>2</sup>	Processing Factors <sup>3</sup>	Anticipated Residue Estimates/Tolerance	
										Acute (Tol., AR, RDF) <sup>6</sup>	Chronic and Cancer (Tol., AR)
Banana	NB/PB	Field trial data and tolerance	40615201	10	0.04, 0.05, 0.02, 0.04, 0.015, 0.015, 0.025, 0.015, 0.03, 0.05	0.03 <sup>6</sup>	100	100	3.9x for dried	RDF 1 TOTALZ=0 TOTALLOD=0 LODRES=0.015 0.04 0.05 0.02 0.04 0.015 0.015 0.025 0.015 0.03 0.05	Tol (0.2)
Barley grain	B	Tolerance	N/A	N/A	N/A	N/A	100	100	2.1x for bran	Tol (0.05)	Tol (0.05)
Field and pop corn grain	B	Tolerance	N/A	N/A	N/A	N/A	100	100	None	Tol (0.05)	Tol (0.05)
Sweet corn grain	NB/PB	Tolerance	N/A	N/A	N/A	N/A	100	100	None	Tol (0.05)	Tol (0.05)
Cottonseed	B	Tolerance	N/A	N/A	N/A	N/A	100	100	None	Tol (0.05)	Tol (0.02)
Oat grain	B	Tolerance	N/A	N/A	N/A	N/A	100	100	2.1x for bran	Tol (0.05)	Tol (0.05)
Rye grain	B	Tolerance	N/A	N/A	N/A	N/A	100	100	None	Tol (0.05)	Tol (0.05)
Water	N/A	EDWCs <sup>4</sup>	N/A	N/A	N/A	N/A	N/A	N/A	N/A	AR (0.000393)	AR (0.000194)
Wheat grain	B	Tolerance	N/A	N/A	N/A	N/A	100	100	2.1x for bran	Tol (0.05)	Tol (0.05)

1. Classification of blended (B), partially blended (PB), not blended (NB).

2. No data were available for percent crop treated, so 100%CT was used in the dietary assessment.

3. Processing study information may be found in the Chemistry Review Document under guideline section 860.1520 Processed Food and Feed (S. Ary, D314891, 10/28/2005).

4. EDWCs = Estimated Drinking Water Concentrations.

5. N/A = Not applicable.

6. LOD = 0.01 ppm for triadimenol and 0.02 for KWG 1342.

## Attachment 2. Acute Food and Water Residue Input File.

U.S. Environmental Protection Agency Ver. 2.02  
 DEEM-FCID Acute analysis for TRIADIMENOL  
 Residue file name: C:\Pesticides\Triazols\Triadimenol\Dietary\triadimenol acute.R98  
 Analysis Date 10-25-2005 Residue file dated: 10-25-2005/21:47:29/8  
 Reference dose (aRfD) = 0.0034 mg/kg bw/day  
 Comment: Food and Water

-----  
 RDL indices and parameters for Monte Carlo Analysis:

Index #	Dist Code	Parameter #1	Param #2	Param #3	Comment
1	6	C:\Pesticides\Triazols\Triadimenol\Dietary\RDF\Banana, NB or PB.rdf			

EPA Comment Code	Crop Grp	Food Name	Def Res (ppm)	Adj. Factors #1	Adj. Factors #2	RDL Pntr
95000230	O	Banana	0.200000	1.000	1.000	1 NB/PB;
Full comment: NB/PB; FTD						
95000231	O	Banana-babyfood	0.200000	1.000	1.000	1 NB/PB;
Full comment: NB/PB; FTD						
95000240	O	Banana, dried	0.200000	3.900	1.000	1 NB/PB;
Full comment: NB/PB; FTD						
95000241	O	Banana, dried-babyfood	0.200000	3.900	1.000	1 NB/PB;
Full comment: NB/PB; FTD						
15000250	15	Barley, pearled barley	0.050000	1.000	1.000	B; Tol
15000251	15	Barley, pearled barley-babyfood	0.050000	1.000	1.000	B; Tol
15000260	15	Barley, flour	0.050000	1.000	1.000	B; Tol
15000261	15	Barley, flour-babyfood	0.050000	1.000	1.000	B; Tol
15000270	15	Barley, bran	0.050000	2.100	1.000	B; Tol
15001200	15	Corn, field, flour	0.050000	1.000	1.000	B; Tol
15001201	15	Corn, field, flour-babyfood	0.050000	1.000	1.000	B; Tol
15001210	15	Corn, field, meal	0.050000	1.000	1.000	B; Tol
15001211	15	Corn, field, meal-babyfood	0.050000	1.000	1.000	B; Tol
15001220	15	Corn, field, bran	0.050000	1.000	1.000	B; Tol
15001230	15	Corn, field, starch	0.050000	1.000	1.000	B; Tol
15001231	15	Corn, field, starch-babyfood	0.050000	1.000	1.000	B; Tol
15001240	15	Corn, field, syrup	0.050000	1.000	1.000	B; Tol
15001241	15	Corn, field, syrup-babyfood	0.050000	1.000	1.000	B; Tol
15001250	15	Corn, field, oil	0.050000	1.000	1.000	B; Tol
15001251	15	Corn, field, oil-babyfood	0.050000	1.000	1.000	B; Tol
15001260	15	Corn, pop	0.050000	1.000	1.000	B; Tol
15001270	15	Corn, sweet	0.050000	1.000	1.000	B; Tol
15001271	15	Corn, sweet-babyfood	0.050000	1.000	1.000	B; Tol
95001280	O	Cottonseed, oil	0.020000	1.000	1.000	B; Tol
95001281	O	Cottonseed, oil-babyfood	0.020000	1.000	1.000	B; Tol
15002310	15	Oat, bran	0.050000	2.100	1.000	B; Tol
15002320	15	Oat, flour	0.050000	1.000	1.000	B; Tol
15002321	15	Oat, flour-babyfood	0.050000	1.000	1.000	B; Tol
15002330	15	Oat, groats/rolled oats	0.050000	1.000	1.000	B; Tol
15002331	15	Oat, groats/rolled oats-babyfood	0.050000	1.000	1.000	B; Tol
15003280	15	Rye, grain	0.050000	1.000	1.000	B; Tol
15003290	15	Rye, flour	0.050000	1.000	1.000	B; Tol
86010000	O	Water, direct, all sources	0.000393	1.000	1.000	
86020000	O	Water, indirect, all sources	0.000393	1.000	1.000	
15004010	15	Wheat, grain	0.050000	1.000	1.000	B; Tol
15004011	15	Wheat, grain-babyfood	0.050000	1.000	1.000	B; Tol
15004020	15	Wheat, flour	0.050000	1.000	1.000	B; Tol
15004021	15	Wheat, flour-babyfood	0.050000	1.000	1.000	B; Tol
15004030	15	Wheat, germ	0.050000	1.000	1.000	B; Tol
15004040	15	Wheat, bran	0.050000	2.100	1.000	B; Tol

**Attachment 3. Acute Food and Water Results File.**

U.S. Environmental Protection Agency Ver. 2.02  
 DEEM-FCID ACUTE Analysis for TRIADIMENOL (1994-98 data)  
 Residue file: triadimenol acute.R98 Adjustment factor #2 used.  
 Analysis Date: 10-25-2005/21:51:44 Residue file dated: 10-25-2005/21:47:29/8  
 Daily totals for food and foodform consumption used.  
 MC iterations = 1000 MC list in residue file MC seed = 1  
 Run Comment: "Food and Water"

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Summary calculations (per capita):

	95th Percentile Exposure	% aRfD	99th Percentile Exposure	% aRfD	99.9th Percentile Exposure	% aRfD
	-----	-----	-----	-----	-----	-----
U.S. Population:	0.000501	14.74	0.000791	23.27	0.001245	36.61
All infants:	0.000798	23.47	0.001244	36.60	0.001657	48.74
Children 1-2 yrs:	0.000981	28.86	0.001367	40.20	0.002047	60.20
Children 3-5 yrs:	0.000871	25.63	0.001158	34.07	0.001609	47.31
Children 6-12 yrs:	0.000639	18.80	0.000857	25.19	0.001220	35.88
Youth 13-19 yrs:	0.000436	12.82	0.000623	18.33	0.001026	30.17
Adults 20-49 yrs:	0.000329	9.68	0.000489	14.39	0.000739	21.74
Adults 50+ yrs:	0.000249	7.33	0.000340	10.00	0.000515	15.15
Females 13-49 yrs:	0.000318	9.34	0.000439	12.92	0.000718	21.13



**Attachment 4. Acute Food Only Results File.**

U.S. Environmental Protection Agency Ver. 2.02  
 DEEM-FCID ACUTE Analysis for TRIADIMENOL (1994-98 data)  
 Residue file: triadimenol acute (food only).R98 Adjustment factor #2 used.  
 Analysis Date: 11-22-2005/10:24:08 Residue file dated: 11-22-2005/10:17:32/8  
 Daily totals for food and foodform consumption used.  
 MC iterations = 1000 MC list in residue file MC seed = 1  
 Run Comment: "Food Only"

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Summary calculations (per capita):

	95th Percentile Exposure	% aRfD	99th Percentile Exposure	% aRfD	99.9th Percentile Exposure	% aRfD
	-----	-----	-----	-----	-----	-----
U.S. Population:	0.000494	14.52	0.000781	22.98	0.001223	35.98
All infants:	0.000763	22.45	0.001191	35.04	0.001663	48.90
Children 1-2 yrs:	0.000961	28.25	0.001342	39.46	0.002027	59.61
Children 3-5 yrs:	0.000862	25.35	0.001137	33.45	0.001573	46.28
Children 6-12 yrs:	0.000633	18.61	0.000851	25.03	0.001215	35.74
Youth 13-19 yrs:	0.000428	12.57	0.000608	17.89	0.001023	30.10
Adults 20-49 yrs:	0.000320	9.42	0.000484	14.22	0.000733	21.56
Adults 50+ yrs:	0.000240	7.07	0.000331	9.74	0.000500	14.71
Females 13-49 yrs:	0.000309	9.08	0.000429	12.61	0.000710	20.90

**Attachment 5. Chronic Food and Water Residue Input File.**

U.S. Environmental Protection Agency Ver. 2.00  
 DEEM-FCID Chronic analysis for TRIADIMENOL 1994-98 data  
 Residue file: C:\Pesticides\Triazols\Triadimenol\Dietary\triadimenol chronic.R98  
 Adjust. #2 used  
 Analysis Date 10-25-2005 Residue file dated: 10-25-2005/22:15:20/8  
 Reference dose (RfD) = 0.0034 mg/kg bw/day  
 Comment: Food and Water

Food Crop			Residue	Adj. Factors		
Comment						
EPA Code	Grp	Food Name	(ppm)	#1	#2	
95000230	O	Banana	0.200000	1.000	1.000	
NB/PB; Full comment: NB/PB; Tol						
95000231	O	Banana-babyfood	0.200000	1.000	1.000	
NB/PB; Full comment: NB/PB; Tol						
95000240	O	Banana, dried	0.200000	3.900	1.000	
NB/PB; Full comment: NB/PB; Tol						
95000241	O	Banana, dried-babyfood	0.200000	3.900	1.000	
NB/PB; Full comment: NB/PB; Tol						
15000250	15	Barley, pearled barley	0.050000	1.000	1.000	B;
Tol						
15000251	15	Barley, pearled barley-babyfood	0.050000	1.000	1.000	B;
Tol						
15000260	15	Barley, flour	0.050000	1.000	1.000	B;
Tol						
15000261	15	Barley, flour-babyfood	0.050000	1.000	1.000	B;
Tol						
15000270	15	Barley, bran	0.050000	2.100	1.000	B;
Tol						
15001200	15	Corn, field, flour	0.050000	1.000	1.000	B;
Tol						
15001201	15	Corn, field, flour-babyfood	0.050000	1.000	1.000	B;
Tol						
15001210	15	Corn, field, meal	0.050000	1.000	1.000	B;
Tol						
15001211	15	Corn, field, meal-babyfood	0.050000	1.000	1.000	B;
Tol						
15001220	15	Corn, field, bran	0.050000	1.000	1.000	B;
Tol						
15001230	15	Corn, field, starch	0.050000	1.000	1.000	B;
Tol						
15001231	15	Corn, field, starch-babyfood	0.050000	1.000	1.000	B;
Tol						
15001240	15	Corn, field, syrup	0.050000	1.000	1.000	B;
Tol						
15001241	15	Corn, field, syrup-babyfood	0.050000	1.000	1.000	B;
Tol						
15001250	15	Corn, field, oil	0.050000	1.000	1.000	B;
Tol						
15001251	15	Corn, field, oil-babyfood	0.050000	1.000	1.000	B;
Tol						
15001260	15	Corn, pop	0.050000	1.000	1.000	B;
Tol						
15001270	15	Corn, sweet	0.050000	1.000	1.000	
NB/PB; Full comment: NB/PB; Tol						
15001271	15	Corn, sweet-babyfood	0.050000	1.000	1.000	
NB/PB; Full comment: NB/PB; Tol						
95001280	O	Cottonseed, oil	0.020000	1.000	1.000	B;

Tol					
95001281 O	Cottonseed, oil-babyfood	0.020000	1.000	1.000	B;
Tol					
15002310 15	Oat, bran	0.050000	2.100	1.000	B;
Tol					
15002320 15	Oat, flour	0.050000	1.000	1.000	B;
Tol					
15002321 15	Oat, flour-babyfood	0.050000	1.000	1.000	B;
Tol					
15002330 15	Oat, groats/rolled oats	0.050000	1.000	1.000	B;
Tol					
15002331 15	Oat, groats/rolled oats-babyfood	0.050000	1.000	1.000	B;
Tol					
15003280 15	Rye, grain	0.050000	1.000	1.000	B;
Tol					
15003290 15	Rye, flour	0.050000	1.000	1.000	B;
Tol					
86010000 O	Water, direct, all sources	0.000194	1.000	1.000	
86020000 O	Water, indirect, all sources	0.000194	1.000	1.000	
15004010 15	Wheat, grain	0.050000	1.000	1.000	B;
Tol					
15004011 15	Wheat, grain-babyfood	0.050000	1.000	1.000	B;
Tol					
15004020 15	Wheat, flour	0.050000	1.000	1.000	B;
Tol					
15004021 15	Wheat, flour-babyfood	0.050000	1.000	1.000	B;
Tol					
15004030 15	Wheat, germ	0.050000	1.000	1.000	B;
Tol					
15004040 15	Wheat, bran	0.050000	2.100	1.000	B;
Tol					

## Attachment 6. Chronic Food and Surface Water Results File.

U.S. Environmental Protection Agency Ver. 2.00  
 DEEM-FCID Chronic analysis for TRIADIMENOL (1994-98 data)  
 Residue file name: C:\Pesticides\Triazols\Triadimenol\Dietary\triadimenol  
 chronic.R98

Adjustment factor #2 used.  
 Analysis Date 10-25-2005/22:15:37 Residue file dated: 10-25-2005/22:15:20/8  
 Reference dose (RfD, Chronic) = 0.0034 mg/kg bw/day  
 COMMENT 1: Food and Water

=====  
 Total exposure by population subgroup  
 =====

Population Subgroup	Total Exposure	
	mg/kg body wt/day	Percent of Rfd
-----		
U.S. Population (total)	0.000251	7.4%
U.S. Population (spring season)	0.000253	7.4%
U.S. Population (summer season)	0.000250	7.3%
U.S. Population (autumn season)	0.000249	7.3%
U.S. Population (winter season)	0.000254	7.5%
Northeast region	0.000249	7.3%
Midwest region	0.000264	7.8%
Southern region	0.000233	6.9%

Triadimenol	Dietary Exposure Assessment - TRED	DP Barcode: 314928
Western region	0.000268	7.9%
Hispanics	0.000280	8.2%
Non-hispanic whites	0.000250	7.4%
Non-hispanic blacks	0.000234	6.9%
Non-hisp/non-white/non-black	0.000249	7.3%
All infants (< 1 year)	0.000469	13.8%
Nursing infants	0.000279	8.2%
Non-nursing infants	0.000541	15.9%
Children 1-6 yrs	0.000643	18.9%
Children 7-12 yrs	0.000359	10.6%
Females 13-19 (not preg or nursing)	0.000195	5.7%
Females 20+ (not preg or nursing)	0.000175	5.1%
Females 13-50 yrs	0.000199	5.9%
Females 13+ (preg/not nursing)	0.000200	5.9%
Females 13+ (nursing)	0.000226	6.6%
Males 13-19 yrs	0.000253	7.4%
Males 20+ yrs	0.000194	5.7%
Seniors 55+	0.000177	5.2%
Children 1-2 yrs	0.000770	22.6%
Children 3-5 yrs	0.000610	17.9%
Children 6-12 yrs	0.000379	11.2%
Youth 13-19 yrs	0.000224	6.6%
Adults 20-49 yrs	0.000188	5.5%
Adults 50+ yrs	0.000178	5.2%
Females 13-49 yrs	0.000181	5.3%

## Attachment 7. Chronic Food Only Results File.

U.S. Environmental Protection Agency Ver. 2.00  
DEEM-FCID Chronic analysis for TRIADIMENOL (1994-98 data)  
Residue file name: C:\Pesticides\Triadimenol\Dietary\triadimenol chronic (food only).R98

Adjustment factor #2 used.  
Analysis Date 11-22-2005/10:33:58 Residue file dated: 11-22-2005/10:33:36/8  
Reference dose (RfD, Chronic) = 0.0034 mg/kg bw/day  
COMMENT 1: Food Only

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### Total exposure by population subgroup

Population Subgroup	Total Exposure	
	mg/kg body wt/day	Percent of Rfd
U.S. Population (total)	0.000247	7.3%
U.S. Population (spring season)	0.000249	7.3%
U.S. Population (summer season)	0.000245	7.2%
U.S. Population (autumn season)	0.000245	7.2%
U.S. Population (winter season)	0.000250	7.3%
Northeast region	0.000245	7.2%

Midwest region	0.000259	7.6%
Southern region	0.000230	6.8%
Western region	0.000264	7.8%
Hispanics	0.000275	8.1%
Non-hispanic whites	0.000246	7.2%
Non-hispanic blacks	0.000230	6.8%
Non-hisp/non-white/non-black	0.000244	7.2%
All infants (< 1 year)	0.000456	13.4%
Nursing infants	0.000274	8.1%
Non-nursing infants	0.000525	15.4%
Children 1-6 yrs	0.000637	18.7%
Children 7-12 yrs	0.000356	10.5%
Females 13-19 (not preg or nursing)	0.000192	5.6%
Females 20+ (not preg or nursing)	0.000171	5.0%
Females 13-50 yrs	0.000195	5.7%
Females 13+ (preg/not nursing)	0.000196	5.8%
Females 13+ (nursing)	0.000220	6.5%
Males 13-19 yrs	0.000250	7.4%
Males 20+ yrs	0.000190	5.6%
Seniors 55+	0.000173	5.1%
Children 1-2 yrs	0.000764	22.5%
Children 3-5 yrs	0.000604	17.8%
Children 6-12 yrs	0.000375	11.0%
Youth 13-19 yrs	0.000221	6.5%
Adults 20-49 yrs	0.000185	5.4%
Adults 50+ yrs	0.000174	5.1%
Females 13-49 yrs	0.000177	5.2%

